**UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF TEXAS**
**TYLER DIVISION**

LIFENET, INC., AIR METHODS CORPORATION, ROCKY MOUNTAIN HOLDINGS, LLC, and EAST TEXAS AIR ONE, LLC,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

U.S. DEPARTMENT OF LABOR,

U.S. DEPARTMENT OF THE TREASURY,

OFFICE OF PERSONNEL MANAGEMENT,

and the

CURRENT HEADS OF THOSE AGENCIES IN THEIR OFFICIAL CAPACITIES,

Defendants.

Case No. _____

**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

This is an action by air ambulance companies challenging, under the Administrative Procedure Act ("APA"), various regulations implementing the "No Surprises Act" of 2020, Pub. L. No. 116-260, div. BB, tit. I, 134 Stat. 1182 (2020), which regulations were promulgated by Defendants: the U.S. Department of Health and Human Services, the U.S. Department of Labor, the U.S. Department of the Treasury, the U.S. Office of Personnel Management (the "Departments"), and the current leaders of those Departments in their official capacities (the "Department Officials").

This action is related to four prior APA challenges to *different* regulations implementing the No Surprises Act, which have been brought by LifeNet and the Texas Medical Association ("TMA"),[1] all of which were assigned to Judge Kernodle. Plaintiffs respectfully request that this case also be assigned to Judge Kernodle.

## INTRODUCTION

1. Plaintiffs provide air ambulance services to patients in this District. Plaintiffs' planes and helicopters transport hundreds of patients each year—many of whom are suffering medical emergencies and would risk death or further serious injury without Plaintiffs' services.

2. The No Surprises Act was a bipartisan compromise: In exchange for pre-empting providers' long-standing right to seek reasonable compensation from the patient, the Act substituted a new "Independent Dispute Resolution" ("IDR") process, in which providers would seek compensation directly from the commercial health plan or health insurer. If the parties could not agree, then they would each submit an "offer" to a neutral arbitrator, known as an "IDR entity," who would determine which offer would be the payment amount.

3. One of the factors to be considered during the IDR process is the Qualifying Payment Amount ("QPA")—a metric created by the Act. The statute provides that the QPA is, typically, the supposed median of the payor's "contracted rates" in 2019, adjusted for inflation. Under the Departments' regulations, the QPA is unilaterally calculated by the payor with no meaningful oversight.

[1] *LifeNet, Inc. v. U.S. Dep't of Health & Hum. Servs., et al.*, No. 22-cv-00162, 2022 WL 2959715 (E.D. Tex. July 26, 2022) (*LifeNet I*); *Tex. Med. Ass'n., et al. v. U.S. Dep't of Health & Hum. Servs., et al.*, 587 F.Supp.3d 528 (E.D. Tex. 2022) (*TMA I*); *Tex. Med. Ass'n., et al. v. U.S. Dep't of Health & Hum. Servs., et al.*, No. 6:22-cv-00372 (E.D. Tex. Sept. 22, 2022) (consolidated case combining complaints filed by TMA and LifeNet).

4. Unfortunately, Defendants failed to provide stakeholders with an opportunity to comment on the challenged regulations before they took effect, as the APA requires. The regulations' many flaws are the predictable result of that failure to consider the views of healthcare providers. The regulations unfairly tilt the calculation of the QPA and disclosures related to the QPA—or lack thereof—heavily in favor of the commercial payors. The regulations are also flawed because they grant payors unfair authority over the timing of payments to healthcare providers and decimate the fairness and efficiency Congress intended for the IDR process.

5. All these flaws are contrary to Congress's statutory directives; are arbitrary and capricious; and are in excess of statutory authority.

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## PARTIES

6. LifeNet, Inc. is an Arkansas not-for-profit corporation operating one fixed-wing and three rotor-wing air ambulances from three airbases. LifeNet's air ambulances routinely transport emergency patients located in this District and in Arkansas, Oklahoma, and Louisiana. LifeNet's headquarters are in Texarkana, Texas.

7. East Texas Air One, LLC is a Limited Liability Company organized under Delaware law, with its principal place of business in Tyler, Texas. From its Tyler location, East Texas Air One carries out air transports using three rotor-wing air ambulances, which routinely transport patients who are located in this District. East Air Texas One is a registered provider with the United States Centers for Medicare and Medicaid Services.

8. Air Methods Corporation ("AMC") is a corporation organized under Delaware law that, through its subsidiaries, operates over 350 fixed-wing and rotor-wing air ambulances from over 260 airbases across the United States, including airbases in this District. AMC routinely transports patients located in this District.

9. Rocky Mountain Holdings, LLC ("Rocky Mountain", and together with AMC, "Air Methods") is a Limited Liability Company organized under Delaware law and is a wholly owned subsidiary of AMC. Rocky Mountain is a billing entity for AMC's operations in Texas, including transports in this District, and is a registered provider with the United States Centers for Medicare and Medicaid Services.

10. Defendant U.S. Department of Health and Human Services is an executive department of the United States headquartered in Washington, D.C.

11. Defendant Xavier Becerra is the Secretary of Health and Human Services. He is sued only in his official capacity.

12. Defendant U.S. Department of the Treasury is an executive department of the United States headquartered in Washington, D.C.

13. Defendant Janet Yellen is the Secretary of the Treasury. She is sued only in her official capacity.

14. Defendant U.S. Department of Labor is an executive department of the United States headquartered in Washington, D.C.

15. Defendant Martin J. Walsh is the Secretary of Labor. He is sued only in his official capacity.

16. Defendant U.S. Office of Personnel Management (OPM) is an executive agency of the United States headquartered in Washington, D.C.

17. Defendant Kiran Ahuja is the Director of OPM. He is sued only in his official capacity.

**JURISDICTION AND VENUE**

18. The Court has subject-matter jurisdiction over this action under 28 U.S.C. § 1331 and 28 U.S.C. § 1346(a).

19. Plaintiffs' causes of action are provided by the APA, 5 U.S.C. §§ 702-706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

20. Venue is proper in this judicial district under 28 U.S.C. § 1391(e). This is an action against Departments of the United States, and the heads of those Departments in their official capacities. LifeNet and East Texas Air One reside in this District, and a substantial part of the events or omissions giving rise to all Plaintiffs' claims occurred in this District.

## BACKGROUND

### I. Plaintiffs' Business Depends Upon Payments by Commercial Insurers

21. Air ambulance providers, like Plaintiffs, are integral to emergency medical care. Air medical services are often the only lifeline that critically ill and injured individuals have to emergency services.

22. Plaintiffs' businesses, and their abilities to continue offering life-saving air ambulance services, depend upon payments by non-government, commercial group health plans and health insurance issuers (collectively "insurers") for services provided by Plaintiffs to emergency patients.

23. Healthcare and air ambulance providers, like Plaintiffs, are typically either "in-network" or "out-of-network" with insurers. An "in-network" provider is one that contracts with the insurer, in advance of any services being provided, to provide services for set rates of payment. Such contracts bar the provider from seeking any additional payment from the insured patient other than the amount of "cost-sharing" (including any copay or deductible) that the patient is required to pay under the terms of the patient's own health plan or insurance policy. An "in-network" provider may also be termed a "participating provider."

24. An "out-of-network" provider has no such pre-service contract in place with the insurer. An "out-of-network" provider may also be termed a "non-participating provider."

25. Plaintiffs would generally prefer to be in-network with contracts specifying reasonable payment rates by agreement with insurers. However, not all insurers are willing to partner with Plaintiffs in this way, so Plaintiffs are out-of-network providers for many insurers of the patients that Plaintiffs transport.

26. East Texas Air One's negotiations, with the largest insurers in this District, were put on hold by those insurers as a result of the No Surprises Act coming into effect. East Texas Air One has now resumed these discussions but remains out-of-network for many insurers.

## II. The IDR Process, Created by the No Surprises Act, Was Intended to Provide Reasonable Compensation to Out-of-Network Providers

27. The No Surprises Act was enacted on December 27, 2020, as part of the Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, div. BB, tit. I, 134 Stat. 1182 (2020). Its relevant requirements went into effect on January 1, 2022. For convenience and simplicity, this Complaint cites the No Surprises Act as codified in the PHS Act, which appears at 42 U.S.C. §§ 300gg-111, 300gg-112, 300gg-131, 300gg-135.[2] The provisions of the Act at issue here are: 42 U.S.C. § 300gg-111, which governs IDRs for emergency medical services other than air ambulances; 42 U.S.C. § 300gg-112, which governs IDRs for air ambulances; and 42 U.S.C. §§ 300gg-131 and 300gg-135, which forbid providers from billing a patient in excess of the patient's "cost sharing" amount.

28. Plaintiffs prefer to obtain reasonable compensation from insurers directly for out-of-network air ambulance services under applicable law. However, when insurers underpaid Plaintiffs for such air ambulance services prior to the enactment of the No Surprises Act, Plaintiffs were often forced to seek reasonable compensation from the patient directly. The possibility that an insurer's member or beneficiary would face greater financial responsibility when the insurer

[2] The NSA made triplicate amendments to provisions of the Public Health Service ("PHS") Act, which is enforced by the Department of Health and Human Services ("HHS"); the Employee Retirement Income Security Act ("ERISA"), which is enforced by the Department of Labor; and the Internal Revenue Code ("IRC"), which is enforced by the Department of the Treasury. The versions of the NSA enacted into ERISA and the IRC are the same in all material respects as the codification in the PHS Act, which is cited in this Complaint.

underpaid Plaintiffs was a significant check on insurers who did not compensate Plaintiffs appropriately.

29. The No Surprises Act removed providers' ability to bill the patient directly for any amount in excess of the patient's "cost sharing" amount. In its place, the Act gave providers a new form of adjudication against insurers: the IDR process.[3] If the IDR process were to break down, or were unable to provide adequate reimbursement, then its failure would imperil Plaintiffs' very survival.

30. The IDR process is similar to "binding final offer arbitration," also referred to as "baseball-style" arbitration. In the IDR process, each party—the provider and the insurer—simultaneously submits its "offer" of the appropriate payment amount for the service at issue. Neither party has the right to see the other's offer or the reasons that the other party gives for it. The IDR entity then picks one of the two offers. The IDR entity's determination is "binding upon the parties involved," absent fraud or misrepresentation, and "shall not be subject to judicial review, except in a case described in [the Federal Arbitration Act]." 42 U.S.C. §§ 300gg-111(c)(5)(E), 300gg-112(b)(5)(E).

31. In determining which offer to select, the No Surprises Act provides that the IDR entity "shall . . . tak[e] into account" a list of "considerations" specified in the statute. 42 U.S.C. §§ 300gg-111(c)(5)(C)(ii), 300gg-112(b)(5)(A). All of these "considerations" (with one exception) are reasonably straightforward, plain-language terms.

[3] The name of the law itself—"No Surprises"—is a reference to the elimination of providers' cause of action against the patients. The name "Independent Dispute Resolution" indicates that Congress intended to provide a method by which providers could obtain reasonable compensation from insurers directly.

32. The one exception is the "qualifying payment amount," or "QPA," which is a term of art coined by the NSA. The QPA is a dollar amount, calculated in secret by the insurer. The QPA is supposed to be calculated, in most cases, as the median of the "contracted rates" that the insurer agreed to pay for similar items or services, in 2019,[4] in the geographic area in which the items or services at issue in the IDR were provided, adjusted for inflation. 42 U.S.C. §§ 300gg-111(a)(3) (non-air-ambulance QPAs), 300gg-112(b)(5)(C)(i)(I) (air ambulance QPAs). According to the Departments, the purpose of the QPA is to "reflect[] market rates under typical contract negotiations." *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,889 (July 13, 2021) ("*IFR Part I*").

## III. The Departments Issue the Implementing Regulations Without Notice-and-Comment

33. Congress instructed the Departments to issue implementing regulations on two discrete areas of the No Surprises Act:

a. *The QPA.* The Departments were instructed to "establish through rulemaking" the "methodology" for "determin[ing]" the QPA; the "information" that the health plan or insurer must "share with the … provider" regarding the QPA; and the "geographic region" whose rates should be considered when calculating the QPA. 42 U.S.C. § 300gg-111(a)(2)(B).

b. *The IDR process.* The Departments were instructed to "establish by regulation one . . . IDR process under which" the IDR entity "determines . . . in accordance with the succeeding provisions of this subsection, the amount of payment" owed to the provider. 42 U.S.C. § 300gg-112(b)(2)(A).

[4] If the insurer did not have sufficient agreements, in 2019, to calculate a median rate (i.e., the insurer had fewer than three such rates) then the insurer is permitted to instead consult a public "database." 42 U.S.C. § 300gg-111(a)(3)(E)(iii)(I). If that insurer had three or more rates in 2020, then the insurer will be permitted, in 2023, to use the median of those rates it paid in 2020. *See id.* (a)(3)(E)(v)(II).

34. On July 13, 2021, the Departments published *IFR Part I*, which contains most of the regulatory provisions challenged in this lawsuit. These *IFR Part I* regulations govern how the QPA is calculated; what information the insurer must disclose about the QPA; and the timing of the insurer's initial payment or denial. As described in more detail below, the challenged regulations in *IFR Part I* greatly exceeded the express delegation of rulemaking authority that Congress granted to the Departments.

35. The APA required the Departments to provide the public with notice, and an opportunity to comment, before issuing *IFR Part I*. *See* 5 U.S.C. § 553(b)(B) (notice-and-comment is required unless the agency shows "good cause"); *see also Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1203 (2015) ("An agency must consider and respond to significant comments received during the period for public comment."). Indeed, this Court previously held as much in earlier suits brought by LifeNet and the Texas Medical Association challenging portions of the interim final rule the Departments issued in October 2021, *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021) ("*IFR Part II*"), which was similarly enacted without notice and comment procedures. *See TMA I*, 587 F. Supp. 3d at 544–48 ("The Departments' failure to comply with the notice-and-comment requirement provides a second and independent basis to hold unlawful and set aside [*IFR Part II*] under the APA."); *LifeNet I*, 2022 WL 2959715 at *9 (same).

36. The Departments knew the importance of receiving and considering comments from stakeholders before issuing *IFR Part I*. During now-HHS Secretary Xavier Becerra's confirmation hearing, Secretary Becerra testified that "we've got to get this arbitration [i.e., the IDR process] provision right."[5] During an April 2021 congressional hearing on HHS's budget

[5] Nomination of Xavier Becerra to Serve as Secretary of Health and Human Services: Hearing before the Senate Comm. on Health, Educ., Lab., and Pensions, 117 Cong. 32 (2021), *available at* https://perma.cc/JG6U-82VT.

request, when asked if he would provide assurance that stakeholder input would not be bypassed for NSA rulemaking, Secretary Becerra testified that, "coming from a background as the [California] attorney general where it was always important to take input whenever we would do rule making or take any action, in court or otherwise, ***I can guarantee you at HHS, before we take an action, we'll take the comments necessary, hear from all the stakeholders*** to make sure what we're doing is based on the facts, the science, and the law. I can guarantee you, sir, you will find we will have gone through a robust process to get there."[6]

37. Contrary to Secretary Becerra's promises, the Departments did not give notice, or an opportunity for public comment, on *IFR Part I*. The Departments' excuses do not suffice to show "good cause" for dispensing with notice-and-comment. *See IFR Part I*, 86 Fed. Reg. at 36,917 (claiming that providing notice and comment would be "impractical"). The Departments could have expedited their internal processes and provided for an abbreviated notice-and-comment period. *See TMA I*, 587 F. Supp. 3d at 544–48; *LifeNet I*, 2022 WL 2959715 at *9.

38. To date—more than one year after promulgating *IFR Part I*—the Departments have still not responded to the public comments they received on these regulations.

## THE CHALLENGED REGULATIONS

39. This Complaint challenges four regulations and one informal guidance document. These flawed rules are discussed below in chronological order—beginning with the provider's submission of its bill to the insurer, and ending with the IDR process.

40. The challenged regulations were codified in the Code of Federal Regulations (C.F.R.) in three separate places. For convenience, this Complaint refers to these rules as codified

[6] FY 2022 Budget Request for the Department of Health and Human Services: Testimony before the House Comm. on Appropriations, 117 Cong. (Apr. 15, 2021) (Statement by X. Becerra), *available at* https://perma.cc/N5DF-FXM3 (at minute 49:06).

at Title 45, Subtitle A (Department of Health and Human Services), Subchapter B (Requirements Relating to Health Care Access), Part 149 (Surprise Billing and Transparency Requirements).[7]

## I. The Departments' Regulation Permits the Insurer to Indefinitely Delay the IDR Process By Delaying Its "Initial Payment" or "Denial" of the Provider's Claim

41. In order to even *begin* the IDR process, a provider must first obtain, from the insurer, an "initial payment"[8] or a "notice of denial of payment." All of the remaining IDR deadlines are keyed to that date. If an insurer delays providing an "initial payment" or "notice of denial of payment," then the provider is unable to initiate the IDR process, and thus the insurer also delays the date on which it must pay the provider. Such delays imperil the cash flow that providers need in order to survive, while allowing insurers to conserve cash and bring inappropriate pressure on providers to accept a lower amount of compensation.

42. In order to prevent this delaying action by the insurers, Congress set a clear deadline in the NSA for when the insurer must provide its "initial payment" or "notice of denial of payment": 30 calendar days from the date the provider submits its "bill" to the insurer. 42 U.S.C. §§ 300gg-111(a)(1)(C)(iv)(I) (the insurer "*shall cover* emergency services … in a manner so that … *not later than 30 calendar days* after the bill for such service is transmitted, [the insurer] sends to the provider … an initial payment or notice of denial of payment" (emphasis added)), *id.* § 300gg-112(a)(3)(B) (same, for air ambulances).

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[7] The Departments also codified these regulations in the C.F.R. under the titles applicable to ERISA and the IRC. *See* 26 C.F.R. § 54.9816-1T *et seq.*; 29 C.F.R. § 2590.716-1 *et seq.* These other codifications are the same, in all material respects, as the codifications in 45 C.F.R. 149, which are cited in this Complaint.

[8] According to the Departments, "the statute's reference to an 'initial' payment does not refer to a first installment. Rather, this initial payment should be an amount that the plan or issuer reasonably intends to be payment in full based on the relevant facts and circumstances and as required under the terms of the plan or coverage[.]" *IFR Part I*, 86 Fed. Reg. at 36,901-36,902.

43. Congress did not delegate to the Departments any authority to deviate, in their rulemaking, from this 30-calendar-day deadline.

44. Nevertheless, the Departments effectively annulled the 30-calendar-day deadline in *IFR Part I*, by adding the following vague caveat: "*the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services*." 45 C.F.R. §§ 149.110(b)(3)(iv)(A) (emphasis added) (non-air ambulance emergency services), 149.130(b)(4)(i) (same, for air ambulances). This regulation is contrary to the statutory text, which sets a clear and unambiguous start date (the date on which "the bill for such services is transmitted" by the provider). The regulation replaces that clear start date with an amorphous start date that is nearly impossible for providers or for the Departments themselves to enforce (the date the insurer "receives the information necessary to decide a claim for payment").

45. This unfortunate rulemaking—promulgated without notice and comment from the public—has led to the predictable result of insurers delaying the date on which they provide their "initial payment" or "notice of denial of payment" by making baseless claims that they need more information in order to do so.

46. When promulgating *IFR Part I*, without notice and comment, the Departments themselves acknowledged that this regulation created the possibility for "abuse and gaming where plans and issuers are unduly delaying making an initial payment or sending a notice of denial to providers on the basis that the provider has not submitted a clean claim." *IFR I*, 86 Fed. Reg. at 36,901. Yet *IFR Part I* contains no mechanism to put a stop to that "abuse and gaming." *IFR Part I* does not define what "information" an insurer can demand from the provider (or from others). *IFR Part I* does not require the insurer to take any affirmative steps to obtain the "information" it claims to need from third-parties like the patient, the patient's secondary/alternative insurance, or

other providers. Nor does *IFR Part I* even require the insurer to tell the provider what "information" the insurer is waiting for.

47. Under the Departments' regulation, a provider has no recourse whenever an insurer takes the position that "the information necessary to decide [the] claim" is information that it can obtain only from the patient, or from the patients' secondary insurance, or from the patients' other healthcare providers, or from anyone else. The provider is made to wait—indefinitely—without even being told the reason why. In the meantime, the insurer keeps the money—indefinitely.

48. The Departments acted arbitrarily and capriciously, and contrary to Congress's express statutory command, when they replaced Congress's clear and mandatory 30-calendar-day deadline with an amorphous start date that effectively extends the deadline indefinitely, and which the Departments themselves foresaw would lead to "abuse and gaming" by insurers.

## II. The Department's Regulation Concerning How the QPA Is Calculated Is Arbitrary and Capricious

49. At the same time that the insurer transmits its "initial payment" or "denial" to the provider, the insurer must also disclose to the provider the "qualifying payment amount," or QPA, for each service code at issue. The QPA is a term of art unique to the No Surprises Act. The QPA is a single dollar amount (per item or service) which Congress intended the insurer to calculate by identifying the median of the "contracted rates" that the insurer agreed to pay in 2019. *See supra,* ¶ 32. The purpose of the QPA, according to the Departments, is to provide an estimate of "market rates under typical contract negotiations." *IFR Part I,* 86 Fed. Reg. at 36,889. The QPA is one of the factors that the IDR entity is directed to consider when deciding which party's offer to accept as the appropriate amount of compensation to the provider. 42 U.S.C. §§ 300gg-111(c)(5)(C)(ii), 300gg-112(b)(5)(A).

50. The regulation governing how the insurer is supposed to calculate the QPA is codified at 45 C.F.R. § 149.140(b) & (c). Although Congress delegated authority to the Departments to make rules on this subject, the result of their rulemaking is so deeply flawed as to be arbitrary and capricious. The QPAs that result from this regulation do not come anywhere close to approximating "market rates under typical contract negotiations," which is the Departments' own stated purpose of the QPA. *IFR Part I,* 86 Fed. Reg. at 36,889.

51. The Departments' regulation allows payors to calculate QPAs that are highly misleading, or that deviate from the statute, in at least five ways:

a. QPAs may be calculated using so-called "ghost rates," meaning rates agreed to by providers that rarely or never provide air-ambulance services;

b. QPAs may be calculated based on rates applicable to very large and diverse geographical regions;

c. QPAs *exclude* incentive-based payments, even though those may be significant contributors to the insurers' "contracted rates";

d. QPAs *exclude* case-specific rates, which are the contracted rates agreed to by out-of-network providers; and

e. Insurers may use contracted rates agreed to by plan administrators.

### A. The Departments' Regulation Allows Insurers to Include, in the QPA, "Ghost Rates" Agreed to By Providers Who Rarely or Never Provide Air Ambulance Services

52. The Departments' regulations permit payors to include, in the QPA calculation, "ghost rates," that is, contracted rates that were agreed to by *providers that rarely or never provide the service at issue*—e.g., a contract with a social worker in which the social worker agrees to a rate for air ambulance services, even though the social worker does not even own or operate an air ambulance. *See generally* 45 C.F.R. § 149.140(a)(1) (defining "contracted rate" as the amount that

the insurer "has contractually agreed to pay" to a provider for the at-issue service, without any requirement that the insurer actually *have paid* that provider for that service even once, and without any requirement that the provider actually be *capable of providing* that service).[9]

53. A provider who does not own or operate an air ambulance will have no incentive to negotiate for a fair price for this service. Therefore, ghost rates are generally lower than rates negotiated by providers who do have this incentive. Including ghost rates in the QPA calculation artificially drives down the QPA and defeats the supposed purpose of the QPA, which the Departments claim is to "reflect[] market rates under typical contract negotiations." *IFR Part I*, 86 Fed. Reg. at 36,889.

54. The Transparency in Coverage Act required payors to disclose their current in-network rates, for a variety of services, on July 1, 2022.[10] Undersigned counsel has retained the expert analysis firm of Dobson DaVanzo to analyze this data. Their investigation was originally submitted as part of Plaintiffs LifeNet and East Texas Air One's challenges to the *IFR Part II, see Tex. Med. Ass'n., et al. v. U.S. Dep't of Health & Hum. Servs., et al.,* ECF 42-1, No. 6:22-cv-00372 (E.D. Tex. Oct. 12, 2022) (Ex. E to Pltfs.' Motion for Summary Judgment), and is attached here as Exhibit A. Their analysis—of one Texas payor—Aetna of Texas—demonstrates that many of

[9] The regulations provide that the QPA is to be calculated using those contracted rates that are "for the same or similar item or service that is provided by a provider in the same or similar specialty." 45 C.F.R. § 149.140(b)(1). "[W]ith respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty." *Id.* (a)(12). "Provider of air ambulance services means an entity that is licensed under applicable State and Federal law to provide air ambulance services." 45 C.F.R. § 149.30. The regulations do not require that the provider actually *provide* air ambulance services, in order for the provider's contracted rate to be included in the QPA.

[10] *See* Transparency in Coverage Act Final Rules, 45 C.F.R. § 147.211(b)(1)(iii); *see also* FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (Aug. 20, 2021), *available at* https://perma.cc/B7L7-QEKM; *see generally* D. Gordon, *New Healthcare Price Transparency Rule Took Effect July 1, But It May Not Help Much Yet*, Forbes.com, July 3, 2022, *available at* https://perma.cc/3YHP-TQQQ.

that payor's contracted rates, for air ambulance services, were agreed to by providers that do not typically operate air ambulances. *See* Ex. A (DaVanzo Decl.). For example, the data shows contracted rates, for air ambulance transport, which were agreed to by social workers, optometrists, and psychologists. *Id*.

55. The Dobson DaVanzo analysis is confirmed by another independent analysis firm, Avalere Health. According to Avalere Health, insurers' QPAs are routinely based on contracts with providers who "rarely or never provide" the service in question.[11] In FAQs issued after *IFR Part I* was published, the Departments recognized "concerns" that inclusion of ghost rates "in the calculation of QPAs may artificially lower the QPA, as these providers have little incentive to negotiate fair reimbursement rates for these service[s]" and sometimes even accept "$0 as their rate."[12] These FAQs confirm that *IFR Part I* does not require that a service actually be "provided by a provider" in order for that service's contracted rate to be included in a QPA. Although the Departments stated that $0 rates should not be included in QPA calculations, they did not say the same for ghost rates that are any amount other than $0, or otherwise indicate that insurers should also exclude from their QPA calculations any non-$0 reimbursement rates associated with services not actually provided. In short, it is the Departments' position that while a $0 ghost rate is excluded

[11] This report is also publicly available online. Avalere Health, *PCP Contracting Practices and Qualified Payment Amount Calculation Under the No Surprises Act*, 1 (August 2, 2022) https://perma.cc/6NJN-ZULQ. Avalere Health concludes that the number of non-specialist providers whose rates are included in the QPA, even though those providers do not actually provide the service at issue, is vastly greater than the number of specialist providers who actually supply the vast majority of these specialty services. *See id.* at 5–6 (noting that primary care physicians massively outnumber "anesthesiologists, emergency physicians, and radiologists," and discussing the reasons why this imbalance means that the QPA is not a credible measure of the market rates for these specialty services).

[12] *FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 55*, U.S. Dep't of Health and Hum. Servs., U.S. Department of Labor, and the U.S. Dep't of the Treasury, Aug. 19, 2022 ("*August 2022 FAQs*"), *available at* https://perma.cc/W4Y3-KFAB

from QPA calculations, a $1 ghost rate is not, although that $1 ghost rate is also for a service that is not provided, and similarly deflates QPAs.

56. The Departments acted arbitrarily and capriciously by permitting insurers to include, in their QPA calculations, "ghost rates" agreed to by providers that may not even provide the service at issue. The low rates that such providers agreed to accept, for a service they knew that they would rarely or never provide, do not "reflect[] market rates under typical contract negotiations," which is the Departments' own stated purpose of the QPA. *IFR Part I,* 86 Fed. Reg. at 36,889.

### B. The Departments' Regulation Allows Insurers to Include, in QPAs, Rates Agreed to By Providers Located In Very Different Geographic Areas

57. The No Surprises Act provides that the QPA, in any given dispute, should include only those "contracted rates" that are "provided in the geographic region" in which the disputed services were provided. 42 U.S.C. § 300gg-111(a)(3)(E)(i). The scope of the "geographic region" is therefore very important because it will affect which "rates" are included in the QPA determination, and which rates are excluded.

58. The Secretary was directed to "establish through rulemaking" the "geographic regions applied for purposes" of the QPA calculation. *Id.* § 300gg-111(a)(2)(B). In that rulemaking, the Secretary was directed to "tak[e] into account access to items and services in rural and underserved areas." *Id.*

59. *IFR Part I* arbitrarily ignores Congress's directive to consider service providers by "geographic region." Whenever the plan or insurer has an insufficient number of "contracted rates" within the state-based region in which the services were provided,[13] the regulations require the

[13] Air ambulance QPAs are calculated by dividing each state into two "geographic regions": "one region consisting of all metropolitan statistical areas . . . in the State," i.e., all urban and suburban

plan or insurer to greatly broaden the geographic scope by including, in the QPA, all of its contracted rates in (1) all metropolitan statistical areas (MSAs, *i.e.*, the urban and suburban areas) *in the Census Division* or (2) all other areas (*i.e.*, the rural areas) in that *Census Division*. 45 C.F.R. §§ 149.140(a)(7)(ii)(B) (air ambulance services), (7)(i)(C) (all other items and services).

60. A Census Division, of which there are only nine nationwide, is an enormous area.[14] For example, the "South Atlantic" Census Division stretches from Delaware down to the Florida Keys.[15] The "Mountain" Census Division extends from Arizona up to Montana.[16] This regulation thus means that a contracted rate for a medical air transport in Alaska's Denali National Park could dictate the QPA for a medical air transport in Los Angeles or Honolulu; and that a contracted rate in the Florida Keys could dictate the QPA in Virginia's Shenandoah Valley.

61. By requiring a calculation tailored to a "geographic region," Congress cannot have meant to dictate payments in one market based on rates agreed to in geographically and economically unique markets that are thousands of miles, and even oceans, apart. The Departments' over-broadening of the term "geographic region" cannot be justified by concern about not having a sufficient number of "contracted rates." Instead, that is a problem of the

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areas, and "one region consisting of all other portions of the State," i.e., all rural areas. 45 C.F.R. § 149.140(a)(7)(ii)(A). But if the insurer has fewer than three contracted rates in this geographic region, then the insurer is directed to broaden the "geographic region" to include the entire *Census Division* in the manner described above in the text. *Id.* (ii)(B). For all other items and services besides air ambulances, then the first region is either (a) the specific MSA in which the items or services were provided or (b) all other areas of the State, outside the MSAs. *Id.* (i)(A). If the insurer has fewer than three contracted rates in this geographic region, then the insurer is directed to broaden the "geographic region" to be either (a) all MSAs in the State; or (b) all other areas of the State, outside the MSAs. *Id.* (i)(B). If the insurer still has fewer than three contracted rates in these broader regions, then the insurer is directed to broaden the "geographic region" to include the entire *Census Division* in the manner described above in the text. *Id.* (i)(C).

[14] *See Census Regions and Divisions of the United States*, U.S. Census Bureau (last visited Oct. 29, 2021), perma.cc/4QWX-7738.

[15] *Id.*

[16] *Id.*

Departments' own making by purposefully excluding substantial volumes of case-specific agreements from the QPA calculation. *See infra* ¶ 69.

62. This expansive definition of "geographic region" also violates Congress's directive that the Departments must account for "access to items and services in rural and underserved areas, including health professional shortage areas" when establishing the "geographic regions." 42 U.S.C. § 300gg-111(a)(2)(B).

**C. The Departments' Regulation Excludes Incentive-Based Payments**

63. The No Surprises Act defines "contracted rate" as "the total maximum payment . . . under such plans or coverage." 42 U.S.C. § 300gg-111(a)(3)(E)(i)(I). The Departments' regulation deviates from that express command by requiring insurers to *exclude* certain portions of the "total maximum payment," if those portions are paid later in time.

64. The Departments recognized that insurers and providers sometimes agree that payments to providers will be "reconciled retrospectively to account for utilization, value adjustments, or other weighting factors that can affect the final payment to a provider" and that insurers and providers also sometimes "agree to certain incentive payments during the contracting process." *IFR Part I*, 86 Fed. Reg. at 36,894.

65. In these arrangements—where the provider agrees that part of its reimbursement will be based in part on the value of the service to the patient, or on some other relevant "weighting factor"—the provider typically accepts a *lower* fixed per-service rate. The idea behind such arrangements is that the provider expects that it will frequently earn the additional, incentive-based payments. If the provider does not believe it will actually earn the additional, incentive-based payments, then the provider will demand a higher fixed per-service rate.

66. "[W]hen calculating median contracted rates" for use in the QPA, however, the Departments command that insurers *only* use the fixed per-service rate, and "*must exclude* risk

sharing, bonus, or penalty, and other incentive-based and retrospective payments or payment adjustments." *Id.* (emphasis added); *see* 45 C.F.R. § 149.140(b)(2)(iv).

67. The Departments offered no textual basis for excluding such payments—which are part of the "total maximum payment" the insurer agreed to pay the provider—from the contracted rates used to calculate QPAs. 42 U.S.C. § 300gg-111(a)(3)(E)(i)(I). Instead, the Departments asserted that "excluding these payments and payment adjustments" is "consistent with how cost sharing is typically calculated for in-network items and services, where the cost-sharing amount is customarily determined at or near the time an item or service is furnished, and is not subject to adjustment based on changes in the amount ultimately paid to the provider or facility as a result of any incentives or reconciliation process." *IFR Part I*, 86 Fed. Reg. at 36,894. Typical calculation of cost-sharing obligations is beside the point, however. The NSA is clear that any amount that is part of the "total maximum payment" under a contract must be included.

68. The Departments' exclusion of incentive-based payments, from the QPA, is directly contrary to the supposed purpose of the QPA, which the Departments claim is to "reflect[] market rates under typical contract negotiations." *IFR Part I,* 86 Fed. Reg. at 36,889. In a "typical contract negotiation," a provider would demand *higher* fixed per-service rates, if the provider were told that it cannot be reimbursed based "risk sharing, bonus, or penalty, and other incentive-based and retrospective payments or payment adjustments." *Id.* at 36,894. The Departments' regulation ignores this obvious feature of market negotiations. The Departments simply pretend that those incentive-based payments don't matter at all to the providers who negotiated for them, and that those providers would have happily agreed to forgo those payments without demanding higher fixed per-service rates in return. This is not a rational market analysis. It is administrative fiat.

### D. The Departments' Regulation Arbitrarily Excludes Case-Specific Contracted Rates from the QPA Calculation

69. The Departments' regulation also deviates from the statute by *excluding* the many thousands of case-specific contracted rates that *out-of-network* providers have negotiated with insurers—even though those rates *do* "reflect[] market rates under typical contract negotiations." *IFR Part I,* 86 Fed. Reg. at 36,889.

70. Case-specific agreements are extremely common in the air ambulance industry because so many providers are out-of-network with most insurers. The Departments acknowledged in *IFR Part I* that "in 2012, 75 percent of [air ambulance] transports were out-of-network and in 2017, 69 percent were out-of-network." *IFR Part I*, 86 Fed. Reg. at 36,923.

71. Many of these case-specific agreements are memorialized in formal, written contracts between the provider and the insurer. Some of these agreements cover more than just the one prior transport, and further provide that the same terms will govern future transports by that provider for patients covered by that insurer.

72. Including these case-specific agreements in the calculation of the QPA would help to achieve the QPA's supposed purpose of "reflecting market rates under typical contract negotiations." *IFR Part I,* 86 Fed. Reg. at 36,889.

73. The No Surprises Act defines the QPA as the "median of the contracted rates recognized by" the insurer. 42 U.S.C. § 300gg-111(a)(3)(E). Under the plain meaning of "contracted rate," a provider's *case-specific* contract with a plan or insurer, negotiated after providing its services to the patient, should be included.

74. The promulgated regulations deviate from the statutory text by explicitly excluding, from the QPA, any "single case agreement, letter of agreement, or other similar arrangement . . .

for a specific participant or beneficiary in unique circumstances." 45 C.F.R. § 149.140(a)(1). Such an agreement, according to the Departments, "does not constitute a contract." *Id.*

75. The Departments' conclusion that a case-specific agreement "does not constitute a contract," 45 C.F.R. § 149.140(a)(1), misunderstands what the term "contract" means.[17] A "contract" is "[a]n agreement between two or more parties creating obligations that are enforceable or otherwise recognizable at law." Black's Law Dictionary (11th ed. 2019). That definition includes a case-specific agreement. Such an agreement contains a promise by the insurer to pay, and a promise by the provider to accept, an agreed rate for the provider's services. These agreements would be enforceable at law if either party breached them.

76. By arbitrarily excluding case-specific agreements from the QPA determinations, the Departments have excluded a very large number of the rates agreed to by providers and insurers that should be included in order to make the QPA better achieve the goal that the Departments themselves set, which is to approximate the "market rate."

### E. The Departments' Regulation Deviates From the Statute By Allowing a Group Health Plan to Use Its Administrator's Rates In Calculating the QPA for Air Ambulances

77. The "sponsor" of a group health plan is a defined term in the ERISA statute; in many cases, the sponsor is the employer of the plan's beneficiaries.[18]

[17] It also conflicts with the Departments' own definitions of a "participating emergency facility" and a "participating health care facility," which provide that a single case agreement constitutes a "contractual relationship" for purposes of those definitions. *See* 45 C.F.R. § 149.30.

[18] "The term "plan sponsor" means (i) the employer in the case of an employee benefit plan established or maintained by a single employer, (ii) the employee organization in the case of a plan established or maintained by an employee organization, (iii) in the case of a plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan, or (iv) in the case of a pooled employer plan, the pooled plan provider." 29 U.S.C. § 1002(16)(B).

78. Congress's definition of the QPA provides that the QPA is to be determined "with respect to all such plans of" the "sponsor."[19]

79. The "administrator" of a group health plan is, in many cases, a *different* entity from the plan's "sponsor." Many employers will, for example, contract with a third party administrator to administer the group health plans that the employer sponsors.[20]

80. The statutory language does not call for the QPA to be determined based on the plans administered by the plan *administrator*. On the contrary, the statute requires the QPA to be calculated "with respect to all such plans of … the *sponsor*." 42 U.S.C. § 300gg-111(a)(3)(E)(i) (emphasis added).

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[19] The No Surprises Act states the following regarding the method of calculating the QPA (with relevant language italicized):

> (i) In general
>
> The term "qualifying payment amount" means, subject to clauses (ii) and (iii), *with respect to a sponsor of a group health plan* and health insurance issuer offering group or individual health insurance coverage—
>
> > (I) for an item or service furnished during 2022, the median of the contracted rates recognized by the plan or issuer, respectively (*determined with respect to all such plans of such sponsor* or all such coverage offered by such issuer that are offered within the same insurance market (specified in subclause (I), (II), (III), or (IV) of clause (iv)) as the plan or coverage) as the total maximum payment (including the cost-sharing amount imposed for such item or service and the amount to be paid by the plan or issuer, respectively) under such plans or coverage, respectively, on January 31, 2019, for the same or a similar item or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item or service is furnished, consistent with the methodology established by the Secretary under paragraph (2)(B), increased by the percentage increase in the consumer price index for all urban consumers (United States city average) over 2019, such percentage increase over 2020, and such percentage increase over 2021.

42 U.S.C. §§ 300gg-111(a)(3)(E)(i) (non-air ambulance IDRs), 300gg-112(c)(2) (for air ambulances, "[t]he term 'qualifying payment amount' has the meaning given such term in section 300gg-111(a)(3) of this title").

[20] *See* 29 C.F.R. § 2510.3-16.

81. The Departments' regulation impermissibly deviates from the statute by permitting a plan sponsor to use, in the QPA calculation, all of the contracted rates of its *plan administrator*:

> (b) Methodology for calculation of median contracted rate—
>
> (1) In general. The median contracted rate for an item or service is calculated by arranging in order from least to greatest the contracted rates of all group health plans of the plan sponsor (*or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable*) . . . .

45 C.F.R. § 149.140(b)(1) (emphasis added). The referenced subparagraph (a)(8)(iv) includes "a third-party administrator contracted by the plan."

82. To illustrate this deviation from the statute: Suppose that the patient's health coverage is provided by a self-insured health plan of the patient's employer, ABC Company (the "sponsor"), and suppose that ABC Company has hired Blue Cross Blue Shield to serve as the administrator of this plan. The *statute* requires the QPA to be calculated based on the median of the rates "recognized" by ABC Company's health care plans for that company's employees. 42 U.S.C. § 300gg-111(a)(3)(E)(i) (QPA is "the median of the contracted rates recognized by the plan . . . determined with respect to all such plans of such sponsor . . . ."). The *regulation*, by contrast, allows Blue Cross Blue Shield (the "administrator") to instead calculate the QPA based on the median of "the contracted rates of … the administering entity," i.e., all of the many rates recognized by *Blue Cross Blue Shield* for all of the many plans that it administers, on behalf of many other companies besides ABC Company. Moreover, there is no disclosure—to the provider or to the IDR entity—of which set of rates has been used to calculate the QPA.

## III. The Departments' Regulation Governing What Information the Insurer Must Disclose, About Its QPA Calculations, Is Arbitrary and Capricious

83. The QPA is determined solely by the insurer based on its own data. The insurer then discloses to the provider the final dollar amount that results from those secret calculations.

84. There is no "discovery" available in the IDR process. Providers and IDR entities have no means, within the IDR process, to determine what the insurer did to calculate the QPA.

85. After the insurer sends the provider its "initial payment" or "notice of denial of payment," together with the QPA, the provider then has an opportunity to request additional, inconsequential information, from the insurer, about how the QPA was calculated.

### A. The Regulation Requires Essentially No Meaningful Disclosure of Important Information Regarding How the QPA Was Calculated

86. The Departments' regulation governing what information the insurer must disclose about the QPA—45 C.F.R. § 149.140(d)—is arbitrary and capricious because it requires almost no meaningful information to be disclosed, even though the Departments acknowledged that providers "need transparency regarding how the QPA was determined." *IFR Part I*, 86 Fed. Reg. at 36,898.

87. The *only* additional information that the insurer must disclose, regarding its secret QPA calculations, is the following:

> (i) Information about whether the qualifying payment amount for items and services involved included contracted rates that were not on a fee-for-service basis for those specific items and services and whether the qualifying payment amount for those items and services was determined using underlying fee schedule rates or a derived amount;
>
> (iii) If a plan or issuer uses an eligible database . . . to determine the qualifying payment amount, information to identify which database was used; and
>
> (iv) If a related service code was used to determine the qualifying payment amount for an item or service billed under a new service code . . . information to identify the related service code; and
>
> (iv) If applicable, a statement that the plan's or issuer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved (as applicable) that were excluded for purposes of calculating the qualifying payment amount.

45 C.F.R. § 149.140(d)(2).

88. These disclosures tell the provider, and the IDR entity, almost nothing of real importance regarding how the QPA was determined.

### B. The Regulation Does Not Allow the Provider or the IDR Entity to Check the Insurers' Work in Calculating the QPA

89. The disclosures required by 45 C.F.R. § 149.140(d)(2) do not even suffice to enable the provider or the IDR entity to verify that the insurer has correctly applied the Departments' QPA methodology. The Departments have *already acknowledged* that some insurers are applying the methodology incorrectly.[21]

90. Aside from this regulation, there is no other meaningful "check" on the accuracy or reliability of insurers' QPA calculations. The Department of Health & Human Services "expects to conduct no more than 9 audits annually" of QPAs. *IFR Part I*, 86 Fed. Reg. at 36,935. That is a very small percentage—significantly less than 1%—of the many thousands of health plans and insurers over whom HHS has supervisory authority, each of whom is likely to be calculating hundreds if not thousands of QPAs each year.

91. The Departments' methodology for calculating the QPA requires the insurer to make a significant number of interpretive decisions requiring independent judgment on issues as

[21] In August 2022, the Departments answered a number of Frequently Asked Questions about implementation of IFR Part I's regulations regarding how to calculate the QPA. *August 2022 FAQs* (Aug. 19, 2022), *available at* https://perma.cc/B7L7-QEKM. These FAQs acknowledge that payors are not consistently calculating the QPA in accordance with the regulations. Specifically, the Departments conceded that they "have been informed" that payors have not been consistently complying with how the Departments intended them to calculate QPAs for providers in the "same or similar specialty." *Id.* at 16–17. The Departments also stated that they "have been informed" that some payors "enter $0 in their fee schedule" for certain items and services; the FAQ instructed payors that "$0 does not represent a contracted rate" and thus "plans and insurers should not include $0 amounts in calculating median contracted rates." *Id.* at 17 n.29. None of these problems were required to be disclosed to the providers or the IDR entities, thanks to the Departments' meager disclosure regulations. Therefore, QPAs infected with those and other problems have been used and are continuing to be used to determine the outcomes of IDR proceedings, without the knowledge of the providers or the IDR entities.

to which reasonable people could disagree. Specifically, in order to calculate the QPA for any given service, the insurer must answer (at least) the following questions for each contracted rate that the insurer includes (or excludes) from the QPA calculation:

(1) Whose contracted rates should be used? As discussed above, the regulation allows a plan *administrator* to use the rates for *all* health plans that the administrator oversees. 45 C.F.R. § 149.140(b)(1). Alternatively, the payor could use the rates of "all group health plans of the plan *sponsor*" (typically, the employer). *Id.* (emphasis added).

(2) What *was* the contracted "rate"? Many insurers' contracts with in-network providers do not contain a simple menu of services, each with a set fee. Some contracts set a rate for a "bundle" of related services, without breaking out each one. Other contracts calculate payments on a "capitation," *i.e.*, a flat payment for all services the patient requires, typically paid over a fixed period of time.[22]

(3) Does the contract that sets this rate also provide for incentive payments (*e.g.*, increased or later payments based on total patient cost, patient outcome, or other variables)? If so, should those incentive payments be included or excluded in the "rate"? What was the dollar amount of the excluded payments? Which payments were included? If the provider performed multiple services, then what portion of the incentive payments should be allocated to the air ambulance rate specifically?

(4) What is the "geographic area" in which each rate was applied in 2019?

(5) What is the "insurance market" for each rate?

(6) What is the "provider specialty" of the provider that agreed to each rate?

*See* 45 C.F.R. § 149.140(c). Each of the foregoing questions is likely to require the application of independent judgment by the insurer in order to determine whether the rate should be included in the QPA determination and even to determine what the "rate" actually was. And yet the

[22] In *IFR Part I*, the Departments instructed the insurers to use a "derived amount" for the rates of services in such cases, *i.e.*, when the contract does not specify the rate for a given service. Calculating the "derived amount" is not straightforward, and the actual amount calculated may vary based on the *purpose* for which the insurer is performing the calculation. *See IFR Part I*, 86 Fed. Reg. at 36,893 (the "derived amount" is "the price that a plan or issuer assigns an item or service for the purpose of internal accounting, reconciliation with providers, or for the purpose of submitting data in accordance with the requirements of 45 CFR 153.710(c)").

Departments' meager disclosure regulation simply assumes that this methodology will always be performed correctly and that providers and IDR entities must simply "take the insurers' word for it."

### C. The Regulation Does Not Require the Insurer to Disclose Any Information About the "Contracted Rates" Used by the Insurer

92. The disclosures required by 45 C.F.R. § 149.140(d)(2) do not tell the provider or the IDR entity how many of the "contracted rates" used in the QPA calculation were "ghost rates" (i.e., rates agreed to by providers that rarely or never provide air ambulance services), or were rates agreed to in very different geographic areas, or were rates based on "derived amounts."[23]

93. In order to evaluate whether a QPA "reflects market rates under typical contract negotiations," *IFR Part I,* 86 Fed. Reg. at 36,889, the IDR entity would need to know the answers to at least the following questions: (1) For each of the rates used in determining the QPA, how often was each rate *actually paid*? Were any of the rates, used in determining the QPA, never paid *at all*? (2) For each rate included in the QPA, what was the specific geographic region in which that rate applied? (3) For each rate included in the QPA, was it a stand-alone rate, or was it instead a "derived amount" assigned by the insurer for internal accounting or other purposes? If so, how was the "derived amount" calculated? The Departments' regulation does not require the insurer to disclose any of this information.

## IV. The Departments Require Two IDRs Per Single Air Transport, In Clear Contravention of the No Surprises Act's Directive to Create an IDR Process In Which IDR Entities Consider Items "Jointly as Part of a Single Determination"

94. After the insurer provides its "initial payment" or "denial," the provider or the insurer may then invoke a 30-business-day "open negotiation" period. If the provider and the

[23] *See supra* note 22 (regulatory definition of "derived amount").

insurer do not agree on a reimbursement rate during that time, then either party may initiate the IDR process.

95. An emergency air transport is billed using two HCPCS codes,[24] which are (i) a base or "lift" rate, plus (ii) a per-mile rate.[25] Those two codes are used to bill for the *same service*. A single emergency transport of a patient will always result in a bill, from the provider, containing charges for each of these two codes, even though the provider only rendered one service: the transport.

96. The statutory text sensibly provides for just *one* IDR process per air ambulance transport, even though a single transport involves two HCPCS codes. The statute repeatedly refers to a single IDR process for a "service"; the statute does not require two separate IDR processes where, as here, a single service involves two HCPCS codes. *See* 42 U.S.C. §§ 300gg-112(b)(1)(B) (if open negotiations fail, the provider may "initiate the independent dispute resolution process . . . with respect to such item or service"), 300gg(b)(2)(A) ("*a* certified IDR entity" shall determine "the amount of payment … for such *services*") (emphasis added); *see also id.* § 300gg-112(c)(1) ("The term 'air ambulance service' means medical transport by helicopter or airplane for patients.").

[24] HCPCS stands for Healthcare Procedure Coding System. *See* HCPCS—General Information, Centers for Medicare & Medicaid Services ("CMS") (last visited Oct. 7, 2022), *available at* https://perma.cc/6LZR-9EM6

[25] A fixed-wing air ambulance transport incurs two HCPCS codes: one, a flat fee for the transport (A0430: Ambulance service, conventional air services, transport, one way (fixed wing) (FW)) and a per-mile rate that is calculated based on the number of miles flown with the patient onboard (A0435: Fixed-wing air mileage, per statute mile). A rotary-wing air ambulance (i.e., a helicopter) has two similar codes: a flat fee (A0431: Ambulance service, conventional air services, transport, one way (a rotary wing) (RW)), and a per-mile fee (A0436: Rotary wing air mileage, per statute mile). *See* https://perma.cc/JK7R-XKKA

97. From the very first IDR processes in which Plaintiffs were involved, earlier this year, until late August of this year, all of the IDR processes were conducted in this way: one IDR process per emergency air transport, in which process the IDR entity determined the payments due to Plaintiffs for both of the two HCPCS codes at issue for that transport.

98. Beginning in late August 2022, however, the Departments began to interpret their own regulations to require *two separate* IDR processes for the *same* transport: one for each of the two HCPCS codes. In other words, under the new regime, one IDR entity may be asked to pick between the insurer's and the provider's offers for the base or "lift" code rate, while a different IDR entity, based on another set of submissions, will be asked to choose between the insurer's and the provider's offers for the per-mile code rate.

99. This requirement—of two separate IDR processes for each air transport—is contrary to Congress's clear direction, to the Departments, to permit IDR entities to consider items and services "jointly as part of a single determination" when the services "are related to the treatment of a similar condition" in order to "encourage[e] the efficiency (including minimizing costs) of the IDR process." 42 U.S.C. §§ 300gg-111(c)(3) (non-air-ambulance IDRs), 300gg-112(b)(3) (these provisions "shall apply" to air ambulance IDRs).

100. The two-IDRs-per-transport requirement is also contrary to common sense. An emergency air ambulance transport is one service for the patient. It is provided by one ambulance, with one medical crew. The provider's submission to the IDR entities, in these two processes, will therefore be exactly the same regarding all but one of the nine statutory factors that are relevant to the IDR entity's determination. The sole exception is the QPA—there will be one QPA based on the insurer's contracted base or "lift" code rates, and a different QPA based on the insurer's contracted per-mile rates. There is no practical reason why a single IDR entity could not make

both determinations (the appropriate base rate, and the appropriate per-mile rate) as part of the same IDR process.

101. This recent directive from the Departments has been communicated to the IDR entities via oral phone calls between Department personnel and the IDR entities. This directive was communicated to undersigned counsel by several IDR entities, after the entities began closing IDR processes and demanding that air ambulance providers re-submit disputes as two separate IDRs. One IDR entity stated that the Centers for Medicare and Medicaid Services ("CMS") had based its oral directive on an informal "Technical Assistance" document that CMS posted on its website: the August 2022 *Technical Guidance for Certified Independent Resolution Entities.*[26] That Technical Assistance document, for the first time, states that services may only be "batched" together if they were "billed under the same service code."[27] This informal guidance purported to interpret the *IFR Part II* regulation concerning "batching," which states as follows:

> (i) In general. Batched items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity only if the batched items and services meet the requirements of this paragraph (c)(3)(i). ….
>
> > (C) The qualified IDR items and services are the same or similar items and services. The qualified IDR items and services are considered to be the same or similar items or services if each is billed under the same service code ….

45 C.F.R. § 149.510(c)(3). Never before had anyone—CMS, the IDR entities, or to Plaintiffs' knowledge any insurer—contended that a "batching" analysis was required in order to come to the common-sense conclusion that a single air transport should be the subject of a single IDR.

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[26] *Technical Guidance for Certified Independent Resolution Entities*, CMS (Aug. 2022), https://perma.cc/R2G9-DW5L

[27] *Id.* at 2 (responding to Topic 1).

102. On September 13, 2022, undersigned counsel sent a letter to the Director of Consumer Information and Insurance Oversight (CCIIO) at CMS, which letter pointed out the absurdity of requiring two separate IDR processes for a single air ambulance transport. Counsel's letter requested that CMS amend its informal "Technical Assistance" document to direct IDR entities to once again treat a single air ambulance transport as requiring just one IDR process, rather than two. On September 15, 2022, counsel had a call with the Deputy Director of CCIIO, and other CCIIO and CMS employees, during which counsel re-iterated this request.

103. On September 28, 2022, an IDR entity told undersigned counsel that there had been a conference call "that morning" with CMS representatives and representatives of all of the certified IDR entities, during which CMS representatives directed the IDR entities that a single air ambulance transport cannot be the subject of a single IDR but must instead receive two IDRs, one for each of the two service codes.

104. CMS has not responded to undersigned counsel's September 13 letter, nor provided any explanation of, or justification for, its new "two IDRs per single transport" requirement.

105. Plaintiffs have begun submitting two IDR initiations, and two IDR "offer" submissions, for each of Plaintiffs' disputed air transports.

106. This has significantly increased the burden of participating in the IDR process. A provider must now pay the IDR fee twice—once for each code—as compared to paying that fee just once. The rule change has also required IDR entities to consider approximately twice the amount of paperwork in submissions relating to air transports.

107. These additional burdens—on providers, insurers, and IDR entities—are particularly onerous because the IDR process system is already overburdened. In the four months between April 15, 2022, and August 11th, 2022, parties initiated over 46,000 IDRs through the

NSA's dispute resolution portal, which is "substantially more" than the 17,000 IDRs that the Departments had expected in a full year.[28]

## V. The Challenged Regulations Harm Plaintiffs

108. The regulations challenged here cause imminent, concrete, and particularized injury to all air ambulance providers, including Plaintiffs. The challenged regulations (i) cause the QPAs to be lower than they otherwise would be, which in turn causes IDR outcomes to be worse for Plaintiffs than they otherwise would be; (ii) deprive Plaintiffs of information about QPAs, which Plaintiffs would otherwise be able to use to assist them in convincing IDR entities that the QPA is not a reliable factor; and (iii) require Plaintiffs to submit two IDR disputes for each air transport, which in turn imposes significantly higher costs on Plaintiffs.

### A. LifeNet's Standing

109. Many of the emergency air ambulance services that LifeNet provides are subject to the No Surprises Act's IDR process. LifeNet provides emergency air ambulance services in Texas, Arkansas, Louisiana, and Oklahoma. LifeNet has conducted many emergency flights transporting patients who were insured by a commercial (*i.e.*, non-Medicare, non-Medicaid) health plan or health insurer, for which LifeNet was an out-of-network provider and which are subject to the No Surprises Act. LifeNet has provided such services since the start of 2022 and anticipates continuing to provide such services through the remainder of 2022 and beyond.

110. As a "nonparticipating provider" of emergency air ambulance services, LifeNet is directly regulated by the challenged regulations. And, as an "object of the Rule, there is 'little question that the [agency] action … has caused [LifeNet] injury.'" *LifeNet I*, 2022 WL 2959715

[28] *Federal Independent Dispute Resolution Process Status Update*, CMS (Aug. 19, 2022), https://perma.cc/A4XW-K65T; *See IFR Part II,* 86 Fed. Reg. 56,056 ("The Departments estimate that there will be approximately 17,000 claims that are submitted to the [dispute resolution] process each year.").

at *6 (quoting *Contender Farms, L.L.P. v. U.S. Dep't of Agric.*, 779 F.3d 258, 264 (5th Cir. 2015)). In any IDR proceeding, it is "LifeNet's services [which] will be analyzed and valued in the IDR process pursuant to the Rule" and "it is LifeNet . . . whose training, experience and quality and outcome measurements are to be considered by the arbitrator." *Id.* at *6–7.

111. LifeNet will suffer injury in IDR processes subject to the regulations challenged here, which "deprive[]" LifeNet "of the arbitration process established by the Act." *LifeNet I,* 2022 WL 2959715 at *7. That process is a "procedural right" that is designed to "protect [LifeNet's] concrete interests" in receiving compensation for its services. *TMA I*, 587 F.Supp.3d at 537.

112. During those IDR processes, it is "LifeNet's services will be analyzed and valued in the IDR process pursuant to the Rule." *LifeNet I,* 2022 WL 2959715 at *7. For example, the arbitrator will be asked to consider the training and experience of the personnel on LifeNet's flights, and LifeNet's quality and outcome measurements. *Id.*

113. Each IDR process results in a determination regarding the value of LifeNet's services. These determinations affect LifeNet's reputation, the market value of LifeNet's services, and the value of the company as a whole.

114. Although LifeNet is compensated for its air ambulance services by AMC pursuant to a contract between the two companies, that contract is of limited duration. Section 2.4 of the contract permits either party to terminate the contract "without cause" after the "two-year anniversary of the Commencement Date," which is October 1, 2023. Section 2.3 of the contract permits the contract's earlier termination due to a "financially inviable situation that is beyond the reasonable expectations of either Party."

115. Due, in part, to the low QPAs disclosed thus far by group health plans and health insurance issuers, LifeNet anticipates that in many (if not all) cases, AMC will continue to submit

offers for LifeNet's services in excess of the QPAs. Should AMC terminate the parties' agreement, LifeNet anticipates that LifeNet, too, would submit offers for its services in excess of the QPAs. The regulations challenged here will "systematically reduce out-of-network reimbursement," *TMA I,* 587 F.Supp.3d at 537, which will cause LifeNet significant economic injury.

116. The regulations challenged here create a significant risk to LifeNet of losing its present contract with AMC. The challenged regulations threaten to create a "financially inviable situation" that would permit AMC to terminate the agreement. In the alternative, the challenged regulations increase the likelihood that AMC will terminate the contract without cause after October 1, 2023.

117. The lower reimbursement rates, determined by IDRs applying the challenged regulations, will immediately cause injury to LifeNet. These lower rates represent a lower dollar valuation for LifeNet's services in the critically important out-of-network commercial payor market. These determinations will instantly devalue LifeNet's services in this market. This injury (lower valuations of LifeNet's services) is for the moment intangible, but it will be converted into tangible economic injury in the near future, whenever LifeNet's current contract with AMC terminates—whether on October 1, 2023, or earlier. By then, the challenged regulations will have depressed the value of LifeNet's services in the commercial-payor market, as a result of all the IDR determinations that will have been decided by that point under the challenged regulations. By depressing the value of LifeNet's services in the commercial-payor market, this will also depress the dollar amount that AMC (or any other commercial partner) would agree to pay for LifeNet's services.

**B. East Texas Air One's and Air Methods' Standing**

118. East Texas Air One and Air Methods routinely perform out-of-network emergency air transports for patients who are covered by insurers. East Texas Air One's and Air Methods'

rights to reimbursement, for these services, are subject to the balance-billing provisions of the NSA.

119. Unlike LifeNet—which is currently compensated for its emergency transports by payment from AMC—East Texas Air One and Air Methods are currently participating in the IDR process to resolve disputes with insurers over appropriate reimbursement rates.

120. East Texas Air One and Air Methods have standing for all of the reasons stated above, for LifeNet. The challenged regulations injure them by "depriv[ing] [them] of the arbitration process established" by the NSA. *TMA I*, 587 F. Supp. 3d at 537. East Texas Air One and Air Methods are also likely to suffer financial harm as a result of the challenged regulations, for all of the reasons stated above for LifeNet.

## CLAIMS FOR RELIEF

### I. COUNT I: The *IFR Part I* Regulation that Annuls Congress's 30-Day Deadline Should Be Set Aside, Under the APA, Because It Is Arbitrary, Capricious, Contrary to Law, In Excess of Statutory Limits, and Contrary to the Statute

**(5 U.S.C. § 706)**

121. Plaintiffs incorporate and re-allege all of the foregoing paragraphs.

122. Congress set a clear deadline in the NSA for when the insurer must provide its "initial payment" or "denial": 30 calendar days from the date the provider submits its claim to the insurer. 42 U.S.C. §§ 300gg-111(a)(1)(C)(iv)(I), 300gg-112(a)(3)(B) (same, for air ambulances).

123. Congress did not grant the Departments authority to alter this clear deadline through rulemaking.

124. The Departments effectively annulled the 30-day deadline in *IFR Part I*, by adding the following: "the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services." 45 C.F.R. §§

149.110(b)(3)(iv)(A) (non-air ambulance emergency services), 149.130(b)(4)(i) (same, for air ambulances).

125. Under Section 706 of the APA, a district court shall "hold unlawful and set aside agency action . . . found to be" either "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. §§ 706(2)(A), (C).

126. This regulation is "in excess of statutory jurisdiction, authority, or limitations," 5 U.S.C. § 706(2)(C), because it deviates from Congress's clear direction.

127. This regulation is also arbitrary, capricious, and an abuse of discretion because it enables "abuse and gaming where plans and issuers are unduly delaying making an initial payment or sending a notice of denial to providers on the basis that the provider has not submitted a clean claim." *IFR Part I*, 86 Fed. Reg. at 36,901.

128. For these reasons, Plaintiffs respectfully request: (1) that this Court set aside and vacate this regulation and (2) that this Court enjoin the Departments and Department Officials from enforcing it.

## II. COUNT II: The *IFR Part I* Regulation Governing How the QPA Is Calculated Should Be Set Aside Because It Is Arbitrary, Capricious, Contrary to Law, In Excess of Statutory Limits, and Contrary to the Statute

**(5 U.S.C. § 706)**

129. Plaintiffs incorporate and re-allege all of the foregoing paragraphs.

130. The purpose of the QPA, according to the Departments, is to provide an estimate of "market rates under typical contract negotiations." *IFR Part I,* 86 Fed. Reg. at 36,889.

131. The regulation governing how the insurer is supposed to calculate the QPA is codified at 45 C.F.R. § 149.140(b) & (c).

132. This regulation is arbitrary and capricious, an abuse of discretion, and contrary to the statute, for five reasons:

a. QPAs may be calculated using "ghost rates" agreed to with providers that rarely or never provide air-ambulance services;

b. QPAs may be calculated based on rates applicable to very large and diverse geographical regions;

c. QPAs *exclude* incentive-based payments, even though those may be significant contributors to the insurers' "contracted rates";

d. QPAs exclude case-specific rates, which are the contracted rates agreed to by out-of-network providers; and

e. Plan sponsors may use contracted rates agreed to by the plan administrators.

133. For those reasons, this regulation is "in excess of statutory jurisdiction, authority, or limitations," 5 U.S.C. § 706(2)(C), because it deviates from Congress's clear direction.

134. For the same reasons, this regulation is also arbitrary, capricious, and an abuse of discretion because it results in distorted QPAs that do not achieve the Department's stated purpose of providing an estimate of "market rates under typical contract negotiations." *IFR Part I,* 86 Fed. Reg. at 36,889.

135. For these reasons, Plaintiffs respectfully request: (1) that this Court set aside and vacate this regulation and (2) that this Court that this Court remand with instructions to the Departments to implement a regulation requiring the QPA to be calculated in a manner that comports with the text and purpose of the NSA.

## III. COUNT III: The *IFR Part I* Regulation that Governs What Information the Insurer Must Disclose, About Its QPA Calculations, Should Be Set Aside, Under the APA,

**Because It Is Arbitrary, Capricious, Contrary to Law, In Excess of Statutory Limits, and Contrary to the Statute**

**(5 U.S.C. § 706)**

136. Plaintiffs incorporate and re-allege all of the foregoing paragraphs.

137. The purpose of the QPA, according to the Departments, is to provide an estimate of "market rates under typical contract negotiations." *IFR Part I,* 86 Fed. Reg. at 36,889.

138. The regulation governing what information the insurer is required to disclose, about the QPA, is codified at 45 C.F.R. § 149.140(d).

139. This regulation does not require meaningful disclosures sufficient to enable the provider or the IDR entity to assess the credibility or the reliability of the QPA.

140. This regulation is therefore "in excess of statutory jurisdiction, authority, or limitations," 5 U.S.C. § 706(2)(C), because it deviates from Congress's clear direction.

141. This regulation is arbitrary, capricious, and an abuse of discretion because it does not require disclosures sufficient to enable providers or IDR entities to assess the credibility or reliability of the QPA or to determine whether the QPA is an estimate of "market rates under typical contract negotiations." *IFR Part I,* 86 Fed. Reg. at 36,889.

142. For these reasons, Plaintiffs respectfully request: (1) that this Court set aside and vacate this regulation; (2) that this Court enjoin the Departments and Department Officials from enforcing it; and (3) that this Court remand with instructions to the Departments to implement a regulation requiring more robust disclosures of the relevant information as described in this Complaint.

## IV. COUNT IV: The Informal "Technical Assistance" Document, Which Requires a Single Air Ambulance Transport to Receive *Two* IDRs, Should Be Set Aside, Under the APA, Because The Guidance Is Arbitrary, Capricious, Contrary to Law, In Excess of Statutory Limits, and Contrary to the Statute

**(5 U.S.C. § 706)**

143. Plaintiffs incorporate and re-allege the foregoing paragraphs.

144. The Departments' recent guidance to IDR entities, requiring that they reject an air ambulance provider's IDR submission unless the provider has initiated *two* IDR processes for the transport (one process for each service code), is contrary to the statute, which provides for a single IDR for each "service," and which also directs the Departments to permit IDR entities to consider items and services "jointly as part of a single determination" when the services "are related to the treatment of a similar condition" in order to "encourage[e] the efficiency (including minimizing costs) of the IDR process." 42 U.S.C. §§ 300gg-111(c)(3) (non-air-ambulance IDRs), 300gg-112(b)(3) (these provisions "shall apply" to air ambulance IDRs). This guidance is therefore "in excess of statutory jurisdiction, authority, or limitations," 5 U.S.C. § 706(2)(C), because it deviates from Congress's clear direction.

145. To the extent that the Departments read their *IFR Part II* regulation, 45 C.F.R. § 149.510(c)(3), to require this outcome, then that regulation, too, is contrary to the statute.

146. This guidance and regulation are also arbitrary, capricious, and an abuse of discretion because requiring two IDR processes is wasteful, duplicative, and needlessly costly, and further risks contradictory rulings from two different IDR entities considering the same transport. The Departments have not provided any valid reason for deviating from Congress's clear direction.

147. There is no practical reason why a single IDR process cannot make a determination as to the appropriate payment due for a single transport under each of the two applicable HCPCS codes. Aside from the QPAs (which will be separately calculated for each code), the remaining statutory factors, that the IDR entity "shall" consider, are exactly the same for both codes.

148. For these reasons, Plaintiffs respectfully request: (1) that this Court set aside and vacate the challenged regulation and guidance; (2) that this Court enjoin the Departments and

Department Officials from enforcing it; and (3) that this Court remand with instructions to the Departments to instruct IDR entities to permit a single emergency air transport to be adjudicated in a single IDR process.

**PRAYER FOR RELIEF**

For the foregoing reasons, Plaintiffs respectfully request that the Court provide the declaratory and injunctive relief set forth in each Count above, and summarized as follows:

A. A judgment declaring that the challenged regulations are arbitrary and capricious and are in excess of statutory authority and limits;

B. A judgment vacating the challenged regulations;

C. A judgment enjoining the Departments and Department Officials from enforcing the challenged regulations; and

D. Any other relief the Court determines to be just and proper.

Date: December 1, 2022

By: */s/ Stephen Shackelford, Jr.*

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